UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,565	12/08/2000	Alan J. McNally	1037US	3261

23690 7590 03/16/2005

Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,565	MCNALLY ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *9,17 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16,18-25 and 27-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-16, 18-25 and 27-49, drawn to a method for determining an analyte in sample, classified in class 435, subclass 6.

II. Claims 9, 17 and 26, drawn to reagents, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case reagent of group I can be used as a probe on an oligonucleotide array, as opposed to its use as a positive control in a molecule assay.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the reagent and the method for determining an analyte in a sample are not coextensive. Group II would require a text search of the method steps in addition to the components necessary to complete the steps which are not required for the search of Group I. Further, even if the nucleotide were known, the method of making a positive control may be novel and unobvious in view of the preamble or active steps.

The inventions of Groups I and II have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I and II together.

Because these inventions are distinct for the reasons given above, have acquired a separate status

in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Marilyn Amiek on February 3, 2005, a provisional election was made without traverse to prosecute the invention of group I, claims 1-8, 10-16, 18-25 and 27-49. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9, 17 and 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 10, 11, 14, 18, 19 and 23, are rejected under 35 U.S.C. 102(b) as being anticipated by Cashman (USPN 5,849,478, 12/15/1998).

Cashman teaches (claims 1, 10 and 18) a method for determining an analyte in a sample suspected of containing said analyte comprising the steps of (see abstract)

a. combining said sample with a single stranded DNA template capable of replication and comprising a starting nucleotide sequence (see col. 5 line 62), a deoxyribonucleotide precursor (see col. 7 line 62), a DNA polymerase enzyme (see col. 8 lines 4-6), a compound capable of generating a detectable signal in the presence of double stranded DNA (see col. 7 lines 61-67, col. 8 line 1), and a primer, said primer linked to a receptor capable of binding with said analyte and comprising a sequence complementary to said starting sequence of said template, under conditions favorable for DNA replication (see col. 8 lines 38-40)

b. monitoring the generation of double stranded DNA by said enzyme by measuring the signal produced by said compound, and (see col. 7 lines 61-67, col. 8 lines 1-3)

c. correlating the production of said signal with the presence or amount of said analyte in said sample (see col. 8 lines 1-3).

With regard to claims 2, 11 and 19, Cashman teaches the analyte a hormome, drug, oligonucleotide or protein (see col. 4 lines 22-23). With regard to claims 6, 14 and 23, Cashman teaches the receptor is an antibody (see col. 9 lines 9-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Salamone et al. (USPN 6,063,908, 05/16/2000).

The teachings of Cashman are described previously.

Cashman does not teach LSD as an analyte.

Salamone et al. teach LSD as an analyte (see abstract).

It would have been prima facie obvious to utilize the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with LSD as taught by Salamone et al. (USPN 6,063,908, 05/16/2000) since Salamone et al. note "The present invention provides hapten derivatives that are useful for the preparation of antigens, antibodies and reagents having superior performance characteristics for use in immunoassays for the detection of LSD and nor-LSD (see abstract first sentence)." Salamone et al. further state " a non-radioisotopic immunoassay method to rapidly detect LSD and its metabolites, especially in urine samples, is highly desirable (see col. 2 lines 39-40)." An ordinary practitioner would have been motivated to use the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) to detect LSD in a sample as taught by Salamone et al. (USPN 6,063,908, 05/16/2000) in order to detect LSD in samples using a non-radioisotopic method with reagents of superior performance characteristics.

5. Claims 4, 5, 12, 13, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Mathies et al. (USPN 5,654,419, 08/05/1997).

The teachings of Cashman are described previously.

Cashman does not teach a modified universal primer or M13 as the template.

Mathies et al. teach a modified universal primer or M13 as the template (see col. 5 lines 50-51).

It would have been prima facie obvious to utilize the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with the primers and template as taught by Mathies et al. (USPN 5,654,419, 08/05/1997) since Mathies et al. note "..subject labels find particular use in sequencing... Thus, various commercial primers are available, such as primers from pUC /M13 (see col. 5 lines46, and 50-51)." An ordinary practitioner would have been motivated to use the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with the

primers as taught by Mathies et al. (USPN 5,654,419, 08/05/1997) since the modified M13 universal primers are commercially available.

6. Claims 7, 8, 15, 16, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Mansfield et al. (*Molecular and Cellular probes*, 1995).

The teachings of Cashman are described previously.

Cashman does not teach PicoGreen.

Mansfield et al. teach a PicoGreen (see p. 153, col. 1 first full paragraph)

It would have been prima facie obvious to utilize the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with PicoGreen as taught by Mansfield et al. (*Molecular and Cellular probes*, 1995) since Mansfield et al. note "Application of these dyes include rapid, sensitive assays for quantitating PCR template DNA, for measuring yield in PCR reactions...(see p. 153, col. 1 first full paragraph, sentence 4)." Mansfield et al. further state, "The sensitivity of OliGreen is reported to be approximately 10,000 times more than absorbance methods for determining oligonucleotide concentrations. Similarly, it has been found that PicoGreen has the same improved sensitivity in PCR template quantification (see p. 153, col. 1 first full paragraph, sentences 5-6)." An ordinary practitioner would have been motivated to use the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with PicoGreen as taught by Mansfield et al. (*Molecular and Cellular probes*, 1995) in order to achieve greater sensitivity in detection of PCR templates.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Liefers et al. (*New England Journal of Medicine*, 1998).

The teachings of Cashman are described previously.

Cashman does not teach carcinoembryonic antigen.

Liefers et al. teach carcinoembryonic antigen (see p. 223, col. 2 lines 14-15).

It would have been prima facie obvious to utilize the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with carcinoembryonic antigen as taught by Liefers et al. (*New England Journal of Medicine*, 1998) since Liefers et al. note "Carcinoembryonic antigen is present in the vast majority of colorectal tumors but not in normal tissues and is therefore a suitable marker of micrometastases...(see p. 223, col. 2 lines 14-18)." Liefers et al. further state, "The development of the reverse-transcriptase PCR assay for carcinoembryonic antigen messenger RNA has made it possible to detect micrometastases in the lymph nodes and bone marrow of patients with colorectal cancer (see p. 223, col. 2 lines 19-23)." An ordinary practitioner would have been motivated to use the method for determining an analyte in a sample as taught by Cashman (USPN 5,849,478, 12/15/1998) with carcinoembryonic antigen as taught by Liefers et al. (*New England Journal of Medicine*, 1998) in order to detect micrometastases.

8. Claims 27, 32, 33, 35, 36, 40, 41, 43, 44, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of the Stratagene Catalog (1988).

The teachings of Cashman are described previously.

Cashman does not teach a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method for determining an analyte in a sample into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been

assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) the other service provided in a kit is quality control" (page 39, column 1).

9. Claims 29, is rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Salamone et al. (USPN 6,063,908, 05/16/2000) in further view of the Stratagene Catalog (1988).

The teachings of Cashman and Salamone et al. are described previously.

The combined teachings of Cashman and Salamone et al. do not teach a kit.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method for determining an analyte (LSD) in a sample into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit

format saves money and resources for everyone by dramatically reducing waste. 2) the other service provided in a kit is quality control" (page 39, column 1).

10. Claims 30, 31, 38, 39, 45 and 46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of in further view of the Stratagene Catalog (1988).

The teachings of Cashman and are described previously.

The combined teachings of Cashman and do not teach a kit.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method for determining an analyte (LSD) in a sample into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) the other service provided in a kit is quality control" (page 39, column 1).

11. Claims 34, 42 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Mansfield et al. (*Molecular and Cellular Probes*, 1995) in further view of the Stratagene Catalog (1988).

The teachings of Cashman and Mansfield et al. are described previously.

The combined teachings of Cashman and Mansfield et al. do not teach a kit.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method for determining an analyte (LSD) in a sample into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) the other service provided in a kit is quality control" (page 39, column 1).

12. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cashman (USPN 5,849,478, 12/15/1998) in view of Liefers et al. (*New England Journal of Medicine*, 1998) in further view of the Stratagene Catalog (1988).

The teachings of Cashman and Liefers et al. are described previously.

The combined teachings of Cashman and Liefers et al. do not teach a kit.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method for determining an analyte (LSD) in a sample into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not

purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) the other service provided in a kit is quality control" (page 39, column 1).

Summary

2. No claims are allowed.

Correspondence

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The

USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600